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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,910	11/28/2000	Hugh J. Pasika	7414.0025	8658

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/724,910	Applicant(s) PASIKA ET AL.	
	Examiner Channing S Mahatan	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-13,16-24,26,27 and 29-45 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4,5,7-13,16-24,26,27 and 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4,5,7-13,16-24,26,27 and 29-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1 Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 21 October 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 34-45. Claims 3, 6, 14, 15, 25, and 28 have been cancelled.

This application contains claim 1, 2, 4, 5, 7-13, 16-24, 26, 27, and 29-33 drawn to an invention(s) non-elected without traverse in the 'Restriction/Election Requirement' mailed 15 January 2002. Applicants are suggested to cancel these claims.

Provisional Obviousness-Type Double Patenting

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used

Art Unit: 1631

to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

Claims 34, 38, and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 14, and 25 of co-pending Application No. 09/911,903. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the broadly encompassing scope of the instantly claimed invention making the inventions to have overlapping embodiments. For example, the aforementioned claims in the pending applications (claim 34 in the instant application versus claim 3 in Application No. 09/911,903) have the similar steps of: 1) receiving a signal representing nucleic acid information; 2) [using a computer], analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call; and 3) making an allele call for the signal if the threshold test is met. Claims 34, 38, and 42 of the instant application are directed to a computer-implemented method, computer readable medium, and system for “processing a signal” (preamble) with the final step of “making a correct allele call”, whereas claims 3, 14, and 25 of co-pending Application No. 09/911,903 are directed to a computer-implemented method, computer readable medium, and system for “making allele calls” (preamble) with the final step of making an allele call. Thus, because of the similar steps (example provided for above) and the final result it would have been obvious that the

Art Unit: 1631

“processing of a signal” as instantly claimed would overlap the embodiments of “making an allele call” (Application No. 09/911,903).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Further, it should be noted this rejection has been set forth in view of Applicants amendment to claims 3, 14, and 25 of co-pending Application No. 09/911,903 on 29 September 2004.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

SCOPE OF ENABLEMENT

The rejection of claims 34-45 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for “analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call” via the disclosed Envelope Caller (as outlined below), does not reasonably provide enablement for the analysis of the signal “to determine if the a signal meets a threshold test of an allele caller making a correct call” by all other means are maintained for reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. It should be noted Applicants have directed the traversal arguments to claims 3, 6, 14, 15, 25, and 28, however, these claims have been previously cancelled. Therefore, the Examiner believes this to be a typographical error and that Applicants arguments are to be directed to claims 34-45 (as rejected in the ‘Office Action’ mailed 09 March 2004).

Art Unit: 1631

Applicants' argue that the Examiner has failed to establish a prima facie case of non-enablement because the Examiner has failed to: 1) explain how those factors establish that one skilled in the art would require undue experimentation to practice the claimed invention; and 2) present any assertions about the level of experimentation that he considers necessary. Applicants arguments are found unpersuasive and are addressed below.

Again, the instant claims broadly embrace other means for "analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call", therefore, the claims are not commensurate in scope with the disclosure. The threshold determination (i.e. threshold test; claim 34) is disclosed as being performed by the Envelope Caller, wherein the specification states:

"Using the three largest energy levels (E1, E2, and E3, respectively – which in the figure corresponds to panels 1, 2, and 5), the Envelope Caller algorithm performs a "threshold determination" (step 314)." (page 15, lines 1-3 of the Specification)

No other procedures are disclosed for threshold determination. As reiterated from the previous 'Office Action' (mailed 09 March 2004), the specification discloses only the following procedures for threshold determination by an Envelope Caller process:

1) Calculate the derivative of the original signal thereby determining the minima and maxima of the original signal; 2) Discard the minima of the original signal; 3) Connect the maxima points of the original signal to obtain an "envelope of the signal"; 4) Calculate the derivative of the "envelope of the signal" to determine the minima and maxima of the "envelope of the signal"; 5) Discard the minima of the "envelope of the signal"; 6) Connect the maxima points of the "envelope of the signal" to obtain a "third signal"; 7) Divide the "third signal" into panels (wherein a panel is defined as one where the signal is initially low, then increases rapidly, and falls off again towards the baseline termination of the minima and maxima); 8) If at least three panels exist calculate the energy level for each panel by summing the square of each element in the panel; 9) Consider only the three regions with the greatest energy; 10) Choose the two dominant peaks in the signal; 11) Make an allele call on the maxima in the two panels with the greatest energy (pages 15-17 of the Specification, Figure 3A, and Figure 7).

Again, none of these above outlined steps or elements are limitations of the instant claims. The specification does not provide guidance, direction, or examples as to other types of signal

Art Unit: 1631

analysis to determine if a signal meets a threshold thereby making an allele call. Therefore, the specification provides only limited guidance (Envelope Caller) to one of skill in the art as for “analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call”. For example, for one of skill in the art to analyze the signal to determine if the signal meets a threshold test of an allele caller making a correct call; one would be required to derive specific criteria(s)/parameter(s) and operation(s)/function(s) suitable to determine if the signal meets a threshold test of an allele caller to make a correct call. In the instant case, for such a derivation to occur one of skill in the art would be required to make independent decisions and judgements regarding: 1) the derivation of the initial governing parameters for a threshold test; 2) ascertain that the threshold test indicates a correct call for an allele caller through testing and validation; 3) derive procedures for the analysis of the signal in order to determine if the signal meets the threshold test of an allele caller to make a correct call. Applicants are directed to *Fields, Wilkinson, and Kende v. Conover and Woodward* [170 USPQ 276; How-to-Make Requirement section] which states:

"the description must place the invention in the possession of the public as fully as if the art or instrument itself had been practically and publicly employed. In order to accomplish this, it must be so particular and definite that from it alone, without experiment or the exertion of his own inventive skill, any person versed in the art to which it appertains could construct and use it."

Such independent decisions, judgments, tests, and validation are not considered to be routine experimentation and one of skill in the art practicing the invention would be required to perform experimentation and utilize inventive skill to develop other means for “analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call” (as broadly encompassed by the instant claims). No other means for “analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call ” are disclosed. None

Art Unit: 1631

appear to have been known in the art. The instant claims embrace more than what is taught in the original disclosure. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. § 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. § 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

The rejection of claims 34, 38, and 42 under 35 U.S.C. § 102(b) as being anticipated by Palsson et al. (Using Quality Measure to Facilitate Allele Calling in High-Throughput Genotyping. Genome Research. Volume 9, pages 1002-1012) is maintained for reasons of record.

Art Unit: 1631

Applicants argue that Palasson et al. fails to perform any threshold test when making an allele call, particularly because Palasson et al. discusses processing allele calls as opposed to using a threshold test to analyze data and determine if an allele call should be made. Applicants' arguments are found unpersuasive and are addressed below.

Palsson et al. describes a computer-implemented method of combining an allele-calling program with quality measures and empirically derived criteria (i.e. peak height and shift) to efficiently and accurately call alleles (Abstract). Again, results (i.e. electropherogram(s); signals representing nucleic acid information) from an allele-calling program are received by the computer program (Decode-GT) and are categorized as good allele calls or bad allele calls, which is based upon a threshold that is established by quality measures, peak heights, and peak shifts (i.e. analyzing procedure; page 1003, right column, lines 45-55; Figures 6, 7, and 8). Allele calls are made for the signal if the threshold is met (represented as the accepted good calls), whereas allele calls that do not meet the threshold (categorized as bad calls) are discarded (page 1003, beginning on the right column line 40 to page 1004, right column, line 4; and page 1010, right column, lines 11-18). Thus, Palsson et al. anticipates the instantly claimed invention.

Claims 34-45 are rejected under 35 U.S.C. § 102(e) as being anticipated by Perlin (U.S. Patent Number 6,807,490 B1).

Perlin discloses a process for analyzing nucleic acid samples that produce quantitative data, and then analyzes this data to characterize a DNA fragment (allele calling) to reduce sizing and quantitation errors in fragment analysis (Abstract; Column 1, lines 5-9; Column 1, lines 57-60; and Column 6, lines 25-34). Signals representing nucleic acid information from DNA sequencers are acquired/received and stored in a file (Columns 8, lines 16-20). The signal

Art Unit: 1631

information is then analyzed and allele calls are made wherein: 1) the largest peak (area or height) is found; 2) all peaks from the signal that either (a) have a DNA length that is not in a window of the allelic ladder, or (b) have a DNA amount that is not within some minimum percentage of the largest peak are removed; 3) calling the alleles by matching the DNA lengths of each sample peak to the DNA sizing windows on the allelic ladder; 4) applying rules to check for possible data artifacts; 5) computation of a quality score; and 6) recording the designated alleles and the quality of the result (claims 34 and 37; Column 23, lines 40-53; and Figure 5). Further, Figure 4 (for example) depicts the signal representing nucleic acid information is used to determine nucleic acid length, the signal information has "at least three panels" for the making an allele call (the signal is bounded by deep local minima), and the signal energy level (claim 35; and refer to below definition in the specification). The inventor further discloses features of a system and software (computer readable medium) for the above described method (claims 38-45; Columns 29-30, lines 59-67 and 1-12, respectively; and Column 32, lines 8-30). Thus, Perlin anticipates the instantly claimed invention.

With respect "panels" it is noted the specification provides the following:

"A panel is a large section of the signal that is bounded by the signal's deep local minima. In Figure 7, 6 panels exist and are bounded as outlined in table 1." (page 14, lines 5-6)

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Art Unit: 1631

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Examiner Initials: *CSM*

Date: *December 12, 2004*

MPW
MICHAEL P. WOODWARD
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TECHNOLOGY CENTER 1600

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